EXHIBIT S

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 1:13-md-2419
This Document Relates to:	)	Judge Rya Zobel
All Actions Against The Saint Thomas Entities	)	

DECLARATION OF JAMES L. GRAY, III, PHARM.D., MBA

James L. Gray, III, declares, under penalty of perjury on the date identified below, as follows:

1. My name is James L. Gray, III. I am the Executive Director of Pharmacy at Barnes-Jewish Hospital in St. Louis, Missouri and have served in that institution's pharmacy leadership position since 1983. I was a member of the Missouri Board of Pharmacy from 1997 through 2002 and served as its President from 2001 until 2002. I am over the age of eighteen and have never been convicted of a felony or crime of moral turpitude.

2. Based on information provided to me regarding Nashville, Tennessee including but not limited to the number of hospitals, community size, availability of medical specialties and medical services, and demographic information (i.e., population, median age, median income, gender and educational background), it is my opinion that St. Louis and Nashville are similar communities. It is my opinion that the standard of care for the oversight and supervision of drug procurement practices in a health system is the same in St. Louis, Nashville or other similar communities. Based upon my education, training and experience, I am familiar with the applicable standard of care for the oversight and supervision of drug procurement practices for a health system as applicable in St. Louis, Missouri and similar communities during 2010 - 2012.

3. Materials Reviewed. In preparation for serving as an expert witness in these proceedings, I reviewed numerous materials including:

- Documents regarding the regulatory history of New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC");
- Information from the United States Centers for Disease Control and Prevention ("CDC"), including the *Morbidity and Mortality Weekly Report* dated December 13, 2002 regarding certain cases of fungal meningitis caused by contaminated epidural steroids made by a compounding pharmacy;
- Information from an October 23, 2003 hearing before the United States Senate's Committee on Health, Education, Labor, and Pensions regarding pharmacy compounding;
- Information published by the United States Food and Drug Administration ("FDA") regarding compounded drug products, compounding pharmacies, and the risks associated with compounded drugs;
- Information published by The American Society of Health System Pharmacists warning the pharmacy and medical community of the risks of using compounded drugs;
- Certain federal, Tennessee and Massachusetts pharmacy laws governing pharmacy compounding;
- The depositions of Debra Schamberg, R.N., John Culclasure, M.D., Jeff Ebel, Carmen Leffler, D.Ph., Martin Kelvas, D.Ph., and Terry Grinder, D.Ph., all with exhibits, as well as portions of the deposition of Michael Schatzlein, M.D.;
- United States Pharmacopeia (USP) (2008) Chapters 795 & 797 which establish national standards for non-sterile and sterile drug compounding respectively;
- NECC invoices to St. Thomas Neurosurgical;
- Saint Thomas Neurosurgical Formulary; and
- Saint Thomas Health system organizational chart.

A list of those materials is attached as Exhibit A.

4. In support of the opinions set forth in this declaration, I have relied on various facts developed in part based on my experience as described above and including but not limited to my experience working with a health system that includes hospitals, ambulatory surgery centers and pain management services. Additionally, I have relied on facts and statements in the materials that I have reviewed including the following:

FACTS

5. Dangers associated with Compounded Drugs: Traditional pharmacy compounding is defined as a process where a pharmacist combines, mixes, or alters ingredients to produce a medication that is custom made to meet a specific medical need based on an individual physician prescription for a specific patient. However, over the 30 years leading up to the NECC disaster (2012) some compounding pharmacies morphed into "non-traditional" pharmacy compounders. Specifically, those pharmacies engaged in production and shipment of large volumes of compounded drugs across state lines, compounded drugs that are essentially copies of FDA-approved commercially available drugs, and compounded drugs outside of a prescriber-patient-pharmacist relationship, i.e. without an individual patient prescription. Those non-traditional compounders provided compounded drugs to third parties for sale, such as hospitals, clinics, physician offices, and home health providers. In effect, those compounding pharmacies operated like manufacturers while hiding under the mantel of state board of pharmacy regulation. In this way they avoided extensive federal regulations (cGMP -21 CFR Parts 210 and 211 enforced by the FDA) designed to insure a supply of safe and effective medications. NECC was one such non-traditional compounding pharmacy operating under state board of pharmacy licensure while compounding slightly modified copies of FDA approved and regulated commercial products (such as methylprednisolone acetate - MPA) from non-sterile bulk chemicals (USP 797 high risk

compounding). NECC then shipped large bulk quantities of those high risk products across state lines without required individual patient prescriptions, for use in epidural steroid injections.

6. NECC offered lower prices than the commercially manufactured FDA approved products while touting that their version of the steroids was preservative free, unlike the FDA approved version of the drugs. However, those compounded drugs were not produced under strict FDA cGMP requirements. Thus, the precise formulation and sterile integrity of those drugs were undocumented. Neither non-traditional nor traditional compounding pharmacies are subject to the same FDA regulations as are FDA licensed manufacturers, and compounded drugs are not FDA approved.

7. As non-traditional compounding emerged in the years preceding 2012 so also did reports of negative health events, some with horrific outcomes, after patients were administered compounded drugs prepared by compounding pharmacies. In fact, the serious risks of non-traditional pharmacy compounding were the subject of extensive public discussion in the pharmacy, medical, and state and federal regulatory communities in the years leading up to 2012.

8. Public health officials warned of the special risks posed by non-traditional compounded drugs. For example, in 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The CDC concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that...follows appropriate measures to ensure that injectable products are free of contamination."

9. In 2001, a Kansas City, Missouri compounding pharmacist, Robert Courtney, supplied an estimated 98,000 adulterated (diluted) doses of IV chemotherapy to more than 4,200 cancer patients over the preceding 11 years, providing only a fraction of the prescribed doses.

Profit was identified as Courtney's motivation. That wrongful conduct went undetected for 11 years because medical observation alone was not sufficient to detect the dilution scheme. In response to the Courtney case, as well as other identified cases of the distribution of adulterated and misbranded sterile products by compounding pharmacies, the Missouri State Board of Pharmacy initiated a routine sampling and testing program for compounded drugs. That program revealed failure rates of approximately 20% for the years 2006-2009, with individual findings ranging from 0% to 450% of labeled potency.

10. In 2003, roughly 1.4 million doses of compounded respiratory solution contaminated with *Burkholderia cepacia* were distributed to patients nationally. The Missouri State Board of Pharmacy found the pharmacy did not adequately recall potentially affected product and failed to advise patients and prescribers of the contamination risk. The Board issued a temporary restraining order, noting in their petition that the pharmacy "engaged in practices that pose a threat of immediate and irreparable injury, loss or damage to patients and presents a probability of serious danger to the health, safety or welfare of the residents of the state."

11. In October 2003, the United States Senate held a hearing regarding regulatory issues in the compounding industry. Experts testified at length regarding the dangers of compounded drugs during that hearing.

12. In 2006 the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the United States during unannounced visits. Twelve (12) of the thirty-six (36) samples (33%) failed analytical testing for either potency or sterility. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

13. In May 2007, the FDA published an article titled "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

14. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

15. The American Society of Health System Pharmacists has also played an active role in warning the pharmacy and medical community of the risks of using compounded drugs. In 2010 they published the "ASHP Guidelines on Outsourcing Sterile Compounding Services." ASHP also developed a "Contractor Assessment Tool" for healthcare organizations to use in conjunction with their guidelines. That document was developed to be used by health systems when deciding whether and from where they should purchase compounded medications.

16. The foregoing is not an exhaustive list of publicly available information regarding the risks associated with compounded drugs; rather it is a representative sample of the types of information available.

17. NECC History: NECC operated a non-traditional compounding pharmacy in Framingham, Massachusetts. Before the meningitis catastrophe that became widely recognized in the fall of 2012, NECC had a history of adverse events relating to its operations.

18. NECC was the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP"). Those complaints and investigations often focused on unsterile conditions at NECC's facilities. For example, in 2002 five patients became ill after receiving epidural injections of bacteria tainted MPA compounded and distributed by NECC. One of those patients died from complications of bacterial meningitis.

A subsequent inspection by the FDA and the MBP identified numerous process and procedural problems at the NECC facility. In 2006 the FDA issued a Warning Letter to NECC. The FDA letter details additional violations at NECC including the sale of compounded drugs without patient-specific prescriptions. Further, the FDA's Warning Letter stated that NECC was compounding copies of commercially available drugs, selling misbranded compounded drugs, and experiencing problems with storage and sterility. That warning letter was available on the FDA's website 6 years before NECC distributed nearly 20,000 doses of fungus contaminated methylprednisolone acetate for use in epidural steroid injections for the symptomatic relief of back pain.

19. Compounded Drugs Require Individual Prescriptions: The preparation, sale and distribution of compounded drugs, in bulk and without individual prescriptions, is unlawful in Tennessee and Massachusetts. In order for drugs to be procured from a compounding pharmacy, patient-specific prescriptions involving the prescriber-patient-pharmacist relationship must be used. *See T.C.A. § 63-10-204(4); Mass. Gen. Law c. 94C, § 17(c); and 21 U.S.C. § 353a.* See, also, deposition of Terry Grinder, D.Ph.

20. Saint Thomas Outpatient Neurosurgical Center: Saint Thomas Outpatient Neurosurgical Center ("Saint Thomas Neurosurgical") is a facility located in Nashville, Tennessee. Although it is licensed as an ambulatory surgery center, per testimony, no neurosurgeons actually work there and no surgeries are performed there. Saint Thomas Neurosurgical specializes in providing epidural steroid injections for the symptomatic relief of spine pain to patients of a neurosurgery group known as the Howell Allen Clinic.

21. According to Michael Schatzlein, M.D., President and CEO of Saint Thomas Health, Saint Thomas Neurosurgical is a for-profit joint venture which is part of the Saint

Thomas Health system. (Schatzlein Dep. at 21:18-22:6, 142:20-25). Saint Thomas Neurosurgical is owned jointly by Saint Thomas Network and Howell Allen Clinic. Saint Thomas Network and Howell Allen Clinic share the profits generated by Saint Thomas Neurosurgical equally. Saint Thomas Network is wholly owned by Saint Thomas Health. Dr. Schatzlein described Saint Thomas Network as a pass through entity with zero employees. (Schatzlein Dep. at 33:13-20). In 2012, the Saint Thomas Hospital Chief Medical Officer and the Saint Thomas Health Chief Financial Officer held seats on the governing board of Saint Thomas Neurosurgical. (Schamberg Dep. at 36:16-37:6)

22. Saint Thomas Neurosurgical is located on the 9th floor of the Medical Plaza East on the Saint Thomas Hospital/Saint Thomas West campus. Saint Thomas Neurosurgical's receptionist, Sheri DeZwaan, wore a name tag bearing the name "Saint Thomas Hospital" at the top. In addition, Dr. Schatzlein testified as follows:

> Q. Do you -- would it surprise you to learn that patients who went to the St. Thomas Outpatient Neurosurgical Center believed that they were receiving care from an entity that was part of the St. Thomas Health system?
>
> A. I guess I'd have to say, no, it wouldn't surprise me. (Schatzlein Dep. at 58:15-21)

23. In 2011 and 2012, Saint Thomas Neurosurgical performed an average of 450 to 500 epidural steroid injections each month. It performed roughly 5,000 epidural steroid injections each year.

24. The Medical Director of Saint Thomas Neurosurgical, Dr. John Culclasure does not receive a salary. He is paid a percentage of collections for the epidural injections that he gives. Specifically, Dr. Culclasure is paid an amount equal to sixty percent (60%) of the collections for each shot that he gives. (Culclasure Dep. at 57:1-15).

25. Saint Thomas Hospital Declines to Purchase from NECC: According to Martin Kelvas D.Ph., former Director of Pharmacy Services for Saint Thomas Hospital, he specifically instructed all pharmacy staff at Saint Thomas Hospital not to purchase drugs from compounding pharmacies. (Kelvas Dep. at 163:14-164:14). Dr. Kelvas testified that, in early 2011, a sales representative from NECC approached Dr. Kelvas in order to solicit Saint Thomas Hospital's business. NECC proposed selling compounded medications in bulk to the hospital. Based upon Dr. Kelvas' general knowledge of pharmacy laws, he did not feel that the proposed arrangement was lawful. (Kelvas Dep. at 104:8-105:6). Accordingly, he declined NECC's solicitation, and he called the Tennessee Board of Pharmacy. (Kelvas Dep. at 105:7-21).

26. Dr. Kelvas then talked with Terry Grinder, D.Ph. of the Tennessee Board of Pharmacy. Dr. Grinder affirmed Dr. Kelvas' interpretation of Tennessee law. Compounded drugs could not be legally purchased from a compounding pharmacy in bulk. Compounded drugs may only be dispensed by a compounding pharmacy, licensed by a board of pharmacy, to fulfill a patient-specific prescription written by a physician (i.e. within the prescriber-patient-pharmacist relationship). (Kelvas Dep. at 96:23-97:5). Dr. Grinder further explained that, in order to procure medications without individual prescriptions, the drugs must be procured from an entity with a manufacturer's license. (Kelvas Dep. at 97:13-22).

27. After confirming that NECC's solicitation was not legal, Dr. Kelvas contacted all hospital pharmacy personnel on the non-profit side of the Saint Thomas Health system (e.g. Saint Thomas West Hospital in Nashville, Baptist Hospital, now known as Saint Thomas Midtown Hospital in Nashville, and MTMC, now known as Saint Thomas Rutherford Hospital in Murfreesboro) and told them what he had learned from Mr. Grinder (i.e., not to purchase from compounding pharmacies). (Kelvas Dep. at 109:24-111:12). However, Saint Thomas Hospital

pharmacy leadership failed to instruct anyone on the for-profit side of its system (such as Saint Thomas Neurosurgical) not to buy in bulk from compounding pharmacies. (Kelvas Dep. at 120:1-12).

28. Dr. Grinder of the Tennessee Board of Pharmacy testified that in Tennessee procuring medications, in bulk and without individual patient prescriptions from compounding pharmacies was unlawful. (Grinder Dep. at 23:18-19, 28:18-22, 29:3-8). Whenever healthcare providers called his office with questions about compounding pharmacies, Dr. Grinder explained that medications could only be procured from compounding pharmacies by using individual prescriptions based upon the prescriber-patient-pharmacist relationship. (Grinder Dep. at 31:13-23). Bulk purchases without prescriptions could not be made from compounding pharmacies. Bulk purchases could only be made from entities with a wholesaler or manufacturer license. NECC did not have such a license. (Grinder Dep. at 28:18-29:4).

29. Saint Thomas Neurosurgical Purchases Injectable Steroids in Bulk from NECC: John Culclasure, M.D. is Saint Thomas Neurosurgical's Medical Director. Debra Schamberg, R.N. is the clinic's Facilities Director. Ms. Schamberg has no pharmacy training. Per testimony, Dr. Culclasure and Ms. Schamberg jointly made the decision for Saint Thomas Neurosurgical to make bulk purchases of methylprednisolone acetate ("MPA") from NECC without individual patient prescriptions. (Culclasure Dep. at 116:2-5; 177:24-178:6; Schamberg Dep. at 56:3-4).

30. In late 2010, Saint Thomas Neurosurgical purchased MPA from a supplier in Nashville, Tennessee known as Clint Pharmaceuticals. The MPA that Saint Thomas Neurosurgical bought from Clint Pharmaceuticals did not come from a compounding pharmacy. Clint Pharmaceuticals only supplied steroids manufactured by FDA regulated pharmaceutical companies. (Ebel Dep. at 26:11-15). All of the MPA purchased by Saint Thomas Neurosurgical

from Clint Pharmaceuticals was manufactured by FDA registered manufacturers, and all contained preservatives. (Ebel Dep. at 26:11-15, 61:13-16).

31. In June of 2011, Saint Thomas Neurosurgical chose to stop buying FDA approved steroids through Clint Pharmaceuticals and started buying compounded MPA from NECC. Saint Thomas Neurosurgical made that change when Clint Pharmaceuticals increased its price for FDA approved generic MPA from $6.49 per vial to $8.95 per vial. Emails sent and received by Ms. Schamberg establish that Saint Thomas Neurosurgical switched from purchasing FDA approved steroids to purchasing compounded steroids from NECC and thereby saved $2.46 per vial. (Schamberg Ex. 39 at pp. 7, 11-16, Ebel Exhibits 284 and 286).

32. Dr. Culclasure and Ms. Schamberg both testified that the decision to purchase from NECC was motivated by an impending shortage of MPA rather than the lower price of the NECC product, or the absence of preservatives. However, testimony by Clint Pharmaceuticals owner Jeffery Ebel confirmed that his firm had sufficient stock of the branded Depo-Medrol to supply all the needs of Saint Thomas Neurosurgical. (Ebel Dep. at 27:1-21). Further, testimony by Dr. Culclasure and Ms. Schamberg that the NECC preservative free product was necessary versus the preserved Depo-Medrol is contradicted by the Neurosurgical Center's previous use of the commercially prepared preserved products with no patient problems noted. (Schamberg Dep. at 70:10-19). Dr. Culclasure also testified that St. Thomas Neurosurgical was not actively looking for a preservative free product. The fact that NECC offered a preservative-free product was simply a "bonus." (Culclasure Dep. at 118:12 – 24). Additionally, the vast majority of epidural steroid injections in the United States was then, and continues to be, done using the preserved commercial products, again with no reported preservative related patient adverse outcomes.

33. Per testimony by Dr. Culclasure and Ms. Schamberg, Saint Thomas Neurosurgical decided to purchase compounded MPA from NECC with no knowledge of Tennessee or federal laws regulating the sale of compounded drugs nor any effort to learn about sterile compounded medications in general or NECC in particular. For example, they did not:

- Understand the substantial difference between a compounding pharmacy and a FDA regulated manufacturer;
- Review publically available FDA and professional publications warning of the dangers of pharmacy compounded sterile drugs;
- Check that NECC held current licensure with Massachusetts, Tennessee and the FDA permitting the bulk sale of compounded MPA;
- Request copies of any state or federal inspection reports, regulatory sanctions or actions or any reports of patient injury or deaths related to administration of NECC's compounded sterile products;
- Verify information contained in NECC's promotional literature; or
- Consult with a pharmacist for competent advice about purchasing non-FDA approved compounded drugs.

(See depositions of Debra Schamberg and John Culclasure, M.D.) Dr. Culclasure and Ms. Schamberg never Googled NECC before they selected NECC to be Saint Thomas Neurosurgical's preferred supplier of injectable MPA. (Schamberg Dep. at 87:20-21; and Culclasure Dep. at 120:22-24)

34. Dr. Culclasure and Ms. Schamberg testified that they carefully reviewed NECC's promotional literature before approving the purchase of MPA from NECC. However, they ignored or else chose not to follow the statement in NECC's own literature concerning the patient specific individual prescription rule:

G. Dispensing

> Product is dispensed by patient-specific prescription only. There must be a specific practitioner-patient-pharmacist relationship to dispense to an individual patient or facility.

(Schamberg Ex. 31, p.10). In spite of that statement, Saint Thomas Neurosurgical proceeded with bulk purchases of MPA from NECC (frequently in 500 vial batches) without using patient-specific prescriptions.

35. Saint Thomas Neurosurgical sends patient lists to NECC: In early to mid-2012, a NECC representative informed Saint Thomas Neurosurgical that NECC needed to receive lists of patients with each order for MPA. (Culclasure Ex. 141 at pp. 8-9). NECC made that request more than six months after Saint Thomas Neurosurgical started making bulk purchases from NECC. The NECC representative explained that NECC needed patient lists in order to comply with Massachusetts Board of Pharmacy requirements. (Culclasure Ex. 141 at pp. 8-9).

36. Ms. Schamberg (Saint Thomas Neurosurgical's Facilities Director) then told the NECC representative that she could not predict which patients would receive MPA. (Schamberg Dep. at 148:15-25). Therefore, Saint Thomas Neurosurgical could not provide lists that would actually correspond with patients who would receive MPA. In response, the NECC representative indicated that any list of patient names would suffice (Culclasure Ex. 141 at pp. 8-9).

37. After receiving that request, Saint Thomas Neurosurgical occasionally sent patient lists to NECC, although it did not send a list with each order. (Culclasure Ex. 141 at pp. 8-9). Saint Thomas Neurosurgical sent those lists even though the lists did not correspond with patients who actually received MPA compounded by NECC. Saint Thomas Neurosurgical sent those lists without regard to patient privacy provisions contained in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

38. Patients Contract Fungal Meningitis and Die: According to Dr. Culclasure, approximately one hundred-thirteen (113) patients got sick after receiving contaminated epidural steroid injections at Saint Thomas Neurosurgical and approximately thirteen (13) patients died. (Culclasure Dep. at 14:8-15).

OPINIONS

I am prepared to offer the following opinions at the trial of this case:

39. Products from compounding pharmacies are inherently less safe and more risky than FDA approved drugs made by FDA licensed pharmaceutical manufacturers. A June 3, 2013 report prepared for Congress by the Congressional Research Service stated that 33% of compounded drugs sampled by the FDA in 2006 failed analytical testing, much higher than commercially prepared and FDA regulated drugs where only 2% failed testing. FDA regulated pharmaceutical manufacturers are required to follow strict manufacturing and quality control standards known as current Good Manufacturing Practices (cGMP – 21 CFR Parts 210 and 211). Those standards are much more stringent, and produce products that are much less likely to contain harmful contaminants or variations in content, than products made by compounding pharmacies. Compounding pharmacies are regulated by state boards of pharmacy and do not operate under the same degree of safety focused scrutiny. Defects in compounded drugs are primarily detected after the products are sold and administered to patients. The stringent pre-release testing required of FDA regulated manufacturers under cGMP insures production errors are less likely to occur. Further, when defects do occur, commercially manufactured drug defects are usually detected prior to distribution.

40. The comparable risks of purchasing from a compounding pharmacy are significant as well as potentially lethal, as demonstrated in case histories from around the country.

41. NECC is a compounding pharmacy and could not lawfully sell compounded drugs in Tennessee except in response to an individual patient prescription based upon a specific prescriber-patient-pharmacist relationship. NECC could not lawfully sell compounded drugs in bulk in Tennessee.

42. During all relevant times, there were FDA approved, commercially manufactured steroids available for use in ESIs. Any purported shortage of steroids for use in ESIs is not factually accurate and in any event would be an insufficient reason to purchase bulk steroids for ESIs from a compounding pharmacy without patient specific prescriptions based on the prescriber-pharmacist-patient relationship.

43. The Saint Thomas Health system (including Saint Thomas Health, St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Neurosurgical) failed to protect the safety of its patients by making sure that no entity, either not-for-profit or for-profit, in the Saint Thomas Health system purchased illegally sold compounded drugs in violation of Tennessee drug laws and in violation of federal drug laws.

44. Dr. Schatzlein, President and CEO of Saint Thomas Health, testified that Saint Thomas Neurosurgical is a for-profit joint venture which is part of the Saint Thomas Health system. (Schatzlein Dep. at 21:18-22:6, 142:20-25). Saint Thomas Health, Saint Thomas Network, Saint Thomas Hospital, and Saint Thomas Neurosurgical, all as part of the Saint Thomas Health system, failed to take appropriate steps to insure that appropriately trained drug procurement personnel were in place at, or available to, Saint Thomas Neurosurgical in order to

protect the safety of patients with regard to the procurement of steroids for use in ESIs. Despite the fact that the pharmacy director of Saint Thomas Hospital confirmed with the Tennessee Board of Pharmacy in early 2011 that NECC could not sell compounded drugs in Tennessee without a patient-specific prescription, and a genuine prescriber-patient-pharmacist relationship, and he communicated that information across the non-profit side of the Saint Thomas Health system, Saint Thomas Health and Saint Thomas Hospital failed to notify personnel on the for-profit side of the system - Saint Thomas Neurosurgical - that purchasing compounded medications, in bulk and without individual prescriptions, was not lawful in Tennessee.

45. All patients of the Saint Thomas Health system, including those of Saint Thomas Neurosurgical, deserve the same degree of care and safety in medication procurement. The failure by the Saint Thomas Health system (including Saint Thomas Health, Saint Thomas Network, Saint Thomas Hospital, and Saint Thomas Neurosurgical) to make sure that medications were not purchased from compounding pharmacies, in bulk and without individual prescriptions and a genuine prescriber-patient-pharmacist relationship, fell below the standard of care for a health system and was negligent and reckless.

46. It was a breach below the applicable standard of care for Saint Thomas Neurosurgical to purchase steroids from a compounding pharmacy, unless a special medical need existed to administer compounded steroids to a particular patient (which it did not), and even if a special medical need did truly exist, it was a breach below the applicable standard of care to purchase steroids from a compounding pharmacy without patient-specific prescriptions and a genuine prescriber-patient-pharmacist relationship. It was a further breach below the applicable standard of care for Saint Thomas Neurosurgical to purchase compounded drugs in bulk from NECC.

47. Saint Thomas Neurosurgical could have purchased FDA approved Depo-Medrol manufactured by Pfizer for a slightly higher price or else it could have purchased another brand of corticosteroid from an FDA approved manufacturer. Saint Thomas Neurosurgical was negligent, reckless and fell below the standard of care in choosing to purchase compounded medications when FDA approved products were available.

48. Based on their deposition testimony, Dr. Culclasure and Ms. Schamberg did not have an appropriate understanding or appreciation of the risks inherent in purchasing from a compounding pharmacy. Untrained employees, without any knowledge of Tennessee or federal drug laws and rules, should not be permitted to make such decisions on their own. The failure of management of Saint Thomas Health and Saint Thomas Network to put adequately trained personnel in drug procurement to at least review the drug purchases of Saint Thomas Neurosurgical fell below the standard of care.

49. Saint Thomas Neurosurgical knew or should have known that medications purchased from NECC could only be acquired and dispensed pursuant to individual patient-specific prescriptions. NECC's promotional literature stated as much. (See Schamberg Ex. 31 at p. 10). In addition, Saint Thomas Neurosurgical would have learned of the individual prescription requirement if it had contacted the Tennessee Board of Pharmacy, as did Dr. Kelvas. In fact, both Dr. Culclasure and Ms. Schamberg testified they knew, or knew of, Dr. Kelvas and could easily have contacted him for guidance. Saint Thomas Neurosurgical was negligent, reckless and fell below the standard of care by not knowing, or neither learning about the rules applicable to pharmacy purchases, nor reviewing publically available information outlining the risks associated with a compounding pharmacy in general.

50. Saint Thomas Neurosurgical, its agents and employees were negligent, reckless and fell below the standard of care when it ignored certain red flags regarding NECC's practices. Specifically, Saint Thomas Neurosurgical overlooked NECC's willingness to distribute pharmacy compounded medications without prescriptions, and it went along with NECC's request for lists of random patient names. NECC's conduct should have alerted Saint Thomas Neurosurgical that NECC was not a trustworthy source for procuring purportedly sterile injectable steroids.

51. It is my opinion that the above described conduct resulted in or caused injuries that otherwise would not have occurred.

I declare under penalty of perjury that the foregoing is a true and correct description of my opinions.

Dated: April 15, 2016

James L Gray, III

James L. Gray, III, PharmD, MBA